

## **REMARKS**

The Office Action of October 9, 2007, has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested in view of the amendments and remarks presented in this response.

Claims 1, 2, 4-8, 11-13, 15 and 25-38 are pending in this application. By this Amendment, claims 4 and 5 have been cancelled and new claim 39 has been added. Accordingly, claims 1, 2, 6-8, 11-13, 15 and 25-39 are currently at issue. All previously pending claims stand rejected.

### **I. Claim Rejections Under 35 USC §103**

#### **A. Claims 1, 2, 6-8, and 27**

In the Office Action, claims 1, 2, and 27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,789,017 to Vanderstraeten ("Vanderstraeten") in view of U.S. Patent No. 4,000,525 to Klawitter et al. ("Klawitter"). Claims 6-8 were further rejected over Vanderstraeten and Klawitter, in further view of U.S. Patent No. 6,228,117 to DeBruijn et al. ("DeBruijn"). Claim 7 was further rejected over Vanderstraeten in view of Klawitter, DeBruijn, and U.S. Patent No. 6,534,084 to Vyakarnam et al. ("Vyakarnam"). Claim 1 has been amended to include the elements of dependent claim 5, which was rejected over Vanderstraeten and Klawitter in view of U.S. Patent No. 4,645,503 to Lin et al. ("Lin") or Vanderstraeten and DeBruijn in view of Lin. Applicants traverse these rejections.

Claim 1, as amended, includes, "the substrate composition degrades upon implantation at a first rate to provide load-bearing support for a period of time and the growth-enhancing composition degrades upon implantation at a second rate faster than the first rate to stimulate new tissue growth on the implant." None of the cited references discloses, teaches, or suggests at least this feature of claim 1.

Vanderstraeten, Klawitter, and Vyakarnam do not disclose this feature of claim 1, and the Office Action does not assert that they do.

The Office Action asserts that Lin and DeBruijn disclose "an implant with different degradation rates." However, the Examiner is incorrect in this regard. Lin merely discloses making modifications to control a single degradation rate at Col. 2, Lns. 46-57 and Col. 5, Lns. 17-25, and does not disclose an implant having two portions with different degradation rates, as

recited in claim 1. For example, Lin states: "If the biodegradation is found to be too rapid, the polymer may be modified ... to increase implant stability or ... to decrease overall binder breakdown rate." (Col. 5, Ln. 20-25). Thus, Lin discloses only modification of a single degradation rate, and not using two different degradation rates. Likewise, the cited portions of DeBruijn (Col. 1, Lns. 37-43) merely disclose a biodegradable prosthetic template. DeBruijn does not disclose an implant having two portions with different degradation rates.

Thus, none of the cited references discloses, teaches, or suggests this feature of claim 1, and no prima facie case of obviousness can be established with respect to claim 1. For the same reasons, no prima facie case of obviousness can be established with respect to claims 2 and 6-8 depending from claim 1.

#### **B. Claims 29-33 and 34-38**

In the Office Action, claims 29, 31, 32, 34, 36, and 37 were rejected as being unpatentable over Vanderstraeten in view of Klawitter. Additionally, claims 30 and 35 were rejected over Vanderstraeten in view of Klawitter and DeBruijn, and claims 33 and 38 were rejected over Vanderstraeten in view of Klawitter and U.S. Patent No. 4,655,777 to Dunn et al. ("Dunn"). Applicants respectfully traverse these rejections.

Independent claims 29 and 34 include, among other features, "a composition for enhancing the rate of bone growth, wherein the composition comprises a biocompatible polymer material and a calcium source." None of the cited references discloses, teaches, or suggests this feature of claims 29 and 34.

The Office Action asserts that Vanderstraeten discloses this feature. Applicants submit that the Office Action is incorrect in this regard. First, Vanderstraeten does not disclose the use of a growth-enhancing composition. Vanderstraeten discloses coating the prosthesis with hydroxyapatite (Col. 4, Lns. 1-8), and Vanderstraeten never discloses or suggests that hydroxyapatite enhances growth of bone. However, even if hydroxyapatite is considered to be a growth-enhancing composition, Vanderstraeten does not disclose forming a composition that includes both a calcium source and a biocompatible polymer. Hydroxyapatite is a ceramic, not a polymer, and while hydroxyapatite contains calcium, Vanderstraeten does not disclose that it serves as a "calcium source." Even if hydroxyapatite is considered to be a calcium source,

Vanderstraeten does not disclose a composition that includes hydroxyapatite and a biocompatible polymer. Thus, Vanderstraeten does not disclose this feature of claims 29 and 34.

DeBruijn also does not disclose this feature, and the Office Action does not assert otherwise. Applicants note that the polymer-ceramic composition disclosed at Col. 6, Lns. 25-26 of DeBruijn (discussed in a previous Office Action) is part of the matrix composition, and is not disclosed for use as part of a growth enhancing composition that coats and/or fills part of a porous structure, as recited in claims 29 and 34. DeBruijn also does not suggest using the polymer-ceramic composition in combination with a calcium source to form such a growth enhancing composition as recited in claims 29 and 34. Applicants also note that DeBruijn discloses that the osteoinductive properties of the disclosed biomaterial are produced by biological factors, such as cells and tissues, present in the biomaterial.<sup>1</sup> (Col. 4, Lns. 17-21). Furthermore, DeBruijn teaches that the use of osteoinductive growth factors is too difficult, and purports to provide a better approach, by using a biomaterial-tissue hybrid structure. (Col. 2, Lns. 23-38). Thus, DeBruijn not only does not disclose this feature, but DeBruijn also teaches away from the use of a growth-enhancing composition as recited in claims 29 and 34.

Klawitter and Dunn do not disclose this feature of claims 29 and 34, and the Office Action does not assert otherwise.

Accordingly, the cited references do not disclose, teach, or suggest at least this feature of claims 29 and 34, and no prima facie case of obviousness can be established with respect to claims 29 and 34. For the same reasons, no prima facie case of obviousness can be established with respect to claims 31-33 and 35-38 depending therefrom.

### **C. Claims 11-13 and 15, and Claims 25, 26, and 28**

In the Office Action, claims 11, 13, 15, 25, and 28 were rejected as being unpatentable over Vanderstraeten in view of Klawitter and DeBruijn. Claims 12 and 26 were further rejected over Vanderstraeten and Klawitter in view of Lin or Vanderstraeten and DeBruijn in view of Lin. Applicants respectfully traverse these rejections.

Claim 11 includes, among other features, “a composition for enhancing the rate of bone growth, wherein the composition includes a polymer material selected from the group consisting

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<sup>1</sup> More specifically, DeBruijn states, “The osteoinductive properties of the biomaterial-tissue hybrid ... is the result of either in vitro formed extracellular bone matrix with osteoinductive properties, the presence of the osteogenic cells, or a combination of these two.”

of polylactic acid, polyglycolic acid, polylactic acid-polyglycolic acid copolymer, polycaprolactone, and combinations thereof.” Similarly, claim 25 includes, among other features, “a growth-enhancing composition including a polymer material selected from the group consisting of polylactic acid, polyglycolic acid, polylactic acid-polyglycolic acid copolymer, polycaprolactone, and combinations thereof.” None of the cited references discloses at least this feature of claims 11 and 25.

As described above with respect to claims 29 and 34, Vanderstraeten does not disclose the use of a composition for enhancing the rate of bone growth, and also does not disclose the use of the recited polymer materials in such a composition.

DeBruijn also does not disclose such a growth-enhancing composition, and does not disclose the use of the recited polymer materials in such a composition. As described above, DeBruijn discloses that the osteoinductive properties of the disclosed biomaterial are produced by biological factors, such as cells and tissues, present in the biomaterial. (Col. 4, Lns. 17-21). Additionally, DeBruijn teaches that the use of osteoinductive growth factors is too difficult, and purports to provide a better approach, by using a biomaterial-tissue hybrid structure. (Col. 2, Lns. 23-38). Thus, DeBruijn not only does not disclose this feature, but DeBruijn also teaches away from the use of a growth-enhancing composition.

Neither Klawitter nor Lin discloses this feature of claims 11 and 25, and the Office Action does not assert otherwise. As an additional matter, Applicants note that the Office Action does not specifically identify where the Examiner believes this feature is disclosed in the cited references. Nevertheless, as described above, Applicants submit that the references do not disclose this feature.

Accordingly, none of the cited references disclose, teach, or suggest at least this element of claims 11 and 25, and no prima facie case of obviousness can be established with respect to claims 11 and 25. For the same reasons, no prima facie case of obviousness can be established with respect to claims 12, 13, 15, 26, and 28 depending therefrom.

#### **D. New Claim 39**

New claim 39 represents previously pending claim 2 rewritten in independent form. Claim 2 was rejected in the Office Action over Vanderstraeten in view of Klawitter. Applicants traverse this rejection.

Claim 39 includes, among other features, “the implant provides mechanical load-bearing support for natural bone structure for a period of time to allow the natural bone structure to grow adjacent the material, and wherein the natural bone structure substantially replaces the implant after the period of time.” The cited references do not disclose, teach, or suggest this feature of claim 39.

The Office Action states, at Page 7, that Vanderstraeten inherently discloses this feature. However, the Examiner has not made the required showing to establish inherency. “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). See also M.P.E.P. 2112 (IV). Here, the Examiner has not attempted to show that the implant of Vanderstraeten necessarily accomplishes the recited feature. Additionally, the portions of Vanderstraeten relied upon by the Examiner cannot support such an inherent disclosure. Vanderstraeten only discloses boney ingrowth into the coating to fix the implant in position, and does not disclose ingrowth into the matrix or replacement of the matrix of the implant.

Further, the implant of Vanderstraeten is not otherwise identical to the implant of the present invention, and thus, inherency cannot be assumed, and the burden of disproving inherency cannot be shifted to Applicants. See M.P.E.P. 2112 (V). The implant of Vanderstraeten contains carbon fibers (in one example, 60% by volume (Col. 2, Ln. 23)), and does not disclose that these carbon fibers will degrade or be resorbed or otherwise replaced by bone over time. Additionally, unlike the claimed implant, the implant of Vanderstraeten is not disclosed to be porous, which would affect the ability of natural bone to ingrow and replace the implant. Thus, it is unlikely that natural bone will substantially replace the implant of Vanderstraeten after a period of time, and the implant of Vanderstraeten is different from the claimed implant. Consequently, Vanderstraeten does not inherently disclose this element of claim 39.

Klawitter does not disclose, teach, or suggest this feature of claim 39, and the Office Action does not assert otherwise.

Accordingly, the cited references do not explicitly or inherently disclose this feature of claim 39, and no prima facie case of obviousness can be established with respect to claim 39.

**II. Priority Date and Presentation**

On Page 7 of the Office Action, the Examiner makes additional statements regarding Dr. Vaidyanathan's presentation and the priority date of Applicants' claims. Applicants have already provided sufficient support to establish that Dr. Vaidyanathan's presentation did not constitute a printed publication, and to clearly establish that at least some of Applicants' claims are entitled to a filing date prior to January 2, 2002. Thus, Applicants choose to rely on the support previously provided and not to make further arguments herein.

**CONCLUSION**

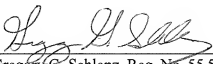
In view of the above amendments and remarks, prompt reconsideration and full allowance of claims 1, 2, 6-8, 11-13, 15 and 25-39 in the subject application are respectfully requested. All rejections have been addressed. Applicants respectfully submit that the instant application is in condition for allowance and respectfully solicit prompt notification of the same.

The Commissioner is authorized to debit or credit our Deposit Account No. 19-0733 for any fees due in connection with the filing of this response.

The Examiner is invited to contact the undersigned at the number set forth below should the Examiner believe that a further conversation would be useful in the prosecution of this case.

Respectfully submitted,

Date: January 9, 2008

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